STATE OF CALIFORNIA

OFFICE OF ADMINISTRATIVE LAW

2001 OAL Determination No. 6

August 7, 2001

Requested by: **ENGINE MANUFACTURERS ASSOCIATION**

Concerning: **OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT AND SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS -- The range of unit risk factors for particulate emissions from diesel-fueled engines determined by the Office of Environmental Health Hazard Assessment and the specific unit risk factor determined by the Scientific Review Panel on Toxic Air Contaminants.**

Determination issued pursuant to Government Code Section 11340.5; California Code of Regulations, Title 1, Section 121 et seq.

ISSUE

Do the range of unit risk factors determined by the Office of Environmental Health Hazard Assessment for particulate emissions from diesel-fueled engines and the specific unit risk factor determined by the Scientific Review Panel on Toxic Air Contaminants constitute "regulations" as defined in Government Code section 11342.600, which are required to be adopted pursuant to the rulemaking provisions of the Administrative Procedure Act?[1]

---

1. The request for determination and three supplements were filed by Timothy A. French of the Law Offices of Neal, Gerber & Eisenberg, Two North La Salle Street, Chicago, Illinois, 60602, (312) 269-8000, counsel for the Engine Manufacturers Association. This request was assigned file number 99-026. The response of the Office of Environmental Health Hazard Assessment and a supplemental attachment were submitted by Colleen Heck, Chief Counsel, OEHHA, 301 Capitol Mall, Room 205, Sacramento, California 95814-4308, (916) 322-

CONCLUSION

The range of unit risk factors determined by the Office of Environmental Health Hazard Assessment and the specific unit risk factor determined by the Scientific Review Panel on Toxic Air Contaminants for particulate emissions from diesel-fueled engines do not constitute "regulations" as defined in Government Code section 11342.600, and therefore, are not subject to the Administrative Procedure Act.

BACKGROUND AND ANALYSIS

In its request for determination, the Engine Manufacturers Association ("Association") asserts that the range of unit risk factors ("URFs") for particulate emissions from diesel-fueled engines determined by the Office of Environmental Health Hazard Assessment ("OEHHA") and the specific URF for particulate emissions from diesel-fueled engines determined by the Scientific Review Panel on Toxic Air Contaminants ("Panel") are "regulations" that are invalid because they were not adopted pursuant to the Administrative Procedure Act ("APA").

OAL's determination of whether the URFs constitute "regulations" subject to the APA depends on (1) whether the APA is generally applicable to the quasi-legislative enactments of OEHHA and the Panel, (2) whether the challenged URFs are "regulations" within the meaning of Government Code section 11342.600 and (3) if they are regulations, whether the challenged URFs fall within any recognized exemption from APA requirements. In the analysis that follows, OAL examines the range of URF's determined by OEHHA and the URF determined by the Panel, separately and independently.

OEHHA

(1) As a general matter, all state agencies in the executive branch of government that are not expressly exempted are required to comply with the rulemaking provisions of the APA when they are engaged in quasi-legislative activities. (*Winzler & Kelly v. Department of Industrial Relations* (1981) 121 Cal.App.3d 120, 126-128, 174 Cal.Rptr. 744, 746-747; Gov. Code, §§ 11342.520 and 11346.) In this connection, the term "state agency" includes, for purposes applicable to the APA,

---

0493. Bruce Reeves, Deputy Attorney General, Department of Justice, 1300 I Street, Suite 125, Sacramento, California, 95814, (916) 324-6058, submitted the response for the Scientific Review Panel on Toxic Air Contaminants. This determination may be cited as "**2001 OAL Determination No. 6**."

"every state office, officer, department, division, bureau, board, and commission." (Gov. Code § 11000.) OEHHA is in the executive branch of state government and not expressly exempted, therefore the APA rulemaking requirements generally apply to quasi-legislative enactments of OEHHA.[2] (See *Poschman v. Dumke* (1973) 31 Cal.App.3d 932, 942, 107 Cal.Rptr. 596, 603 (an agency created by the Legislature is subject to and must comply with the APA).)

(2) Government Code section 11340.5, subdivision (a), prohibits state agencies from issuing rules without complying with the APA. It states as follows:

> "(a) No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a ['']regulation['] as defined in Section 11342.600, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]."

Government Code section 11342.600, defines "regulation" as follows:

> ". . . every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure."

Under Government Code section 11342.600, a rule is a "regulation" for these purposes if (1) the challenged rule is either a rule or standard of general application or a modification or supplement to such a rule, and (2) the challenged rule has been adopted by the agency to either implement, interpret, or make specific the law enforced or administered by the agency or govern the agency's procedure. (See *Grier v. Kizer* (1990) 219 Cal.App.3d 422, 440, 268 Cal.Rptr. 244, 251; *Union of American Physicians & Dentists v. Kizer* (1990) 223 Cal.App.3d 490, 497, 272 Cal.Rptr. 886, 890.)

In 1983, Health and Safety Code section 39650 et seq., commonly referred to as the Tanner Act, was enacted. The Tanner Act, in relevant part, clarified that only the Air Resources Board ("ARB") has the authority to identify in regulation substances that are toxic air contaminants ("TACs") and also to adopt in regulation

---

2. For a detailed analysis of the applicability of the APA to quasi-legislative enactments of OEHHA, see 1999 OAL Determination No. 17 (California Regulatory Notice Register 99, No. 33-Z, August 13, 1999, p. 1575).

airborne toxic control measures for TACs. (Health & Saf. Code, §§ 39656 through 39659, 39662, and 39665 through 39669.5.) Health and Safety Code section 39655, subdivision (a), defines a TAC in relevant part as ". . . an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health . . . ."

The Tanner Act has two distinct yet interrelated phases or steps: (1) the TAC identification process, which is also known as the risk assessment stage, and (2) the risk management or control phase. The risk management phase only occurs if ARB identifies a substance as a toxic air contaminant.

An overview of the TAC identification process in effect at the time of the request for determination (Health & Saf. Code, §§ 39660 – 39662[3]) is helpful in resolving the issue before us. ARB requests OEHHA, and works in consultation with OEHHA, to evaluate the health effects of substances in order to prepare recommendations regarding those substances " . . . which may be determined to be [TACs]."[4] OEHHA ". . . shall consider all available scientific data . . ."[5] before submitting its written evaluations and recommendations to ARB. ARB and OEHHA then prepare a report which is made available to the public. The report is then submitted to the Panel for a review of ". . . the scientific procedures and methods used to support the data, the data itself, and the conclusions and assessments on which the report is based."[6] The Panel either returns the report to ARB and OEHHA for revisions or submits its written findings to the ARB. Within 10 working days of receipt of the Panel's findings, ARB must begin the APA rulemaking process by preparing a hearing notice and a proposed regulation for purposes of determining if the substance is a TAC.

The Association's request for determination deals solely with the range of URFs determined by OEHHA and the specific URF determined by the Panel which occurred during the TAC identification process. A URF is an estimate or statistical likelihood of excess cancer occurrence in a given population exposed to a given substance. The Association characterizes a URF as the ". . . risk per microgram per cubic meter of daily exposure during an assumed 70-year lifetime."[7] Another definition of a URF is as follows:

---

3. Health and Safety Code section 39660 was amended effective January 1, 2000 (Stats. 1999, ch. 731, § 5), but those amendments do not alter the outcome of this determination.
4. Health and Safety Code section 39660, subdivision (a).
5. *Id*.
6. Health and Safety Code section 39661, subdivision (b).
7. Association request for determination, page 1.

> "The number of potential excess cancer cases from a lifetime exposure to one microgram per cubic meter (μ/m^3) of a given substance. For example, a unit risk value of $5.5x10^{-6}$ would indicate an estimated 5.5 cancer cases per million people exposed to an average concentration of 1 μ/m^3 of a specific carcinogen for 70 years."[8]

We now address the issue of whether the range of URFs determined by OEHHA[9] is a rule or standard of general application. In this regard, Health and Safety Code section 39660, subdivision (a), mandates in relevant part that the TAC identification process begins with ARB requesting OEHHA ". . . in consultation with and *with the participation of . . . [ARB] . . .*" to ". . . *evaluate* the health effects of and *prepare recommendations* regarding substances, other than pesticides in their pesticidal use, which may be or are emitted into the ambient air of California and which may be determined to be toxic air contaminants . . . ." (Emphasis added.) At this point OEHHA is functioning as a consultant or in an advisory capacity.

OEHHA's statutory mandate is as follows:

> "In conducting this evaluation, [OEHHA] shall *consider all available scientific data*, including, but not limited to, relevant data provided by [ARB], the State Department of Health Services, the Occupational Safety and Health Division of the Department of Industrial Relations, the Department of Pesticide Regulation, international and federal health agencies, private industry, academic researchers, and public health and environmental organizations. [Health & Saf. Code, § 39660, subd. (b).]"

Section 39660's requirement that OEHHA survey and consider all available scientific data is a review and analysis function. OEHHA is then mandated to ". . . *assess* the availability and quality of data on health effects, including potency, mode of action, and other relevant biological factors, of the substance."[10] OEHHA's assessment must also contain an ". . . *estimate* of the levels of exposure which may cause or contribute to adverse health effects . . ."[11] along with an exposure level below which no adverse health effects are anticipated and also an ample margin of safety accounting for specified factors. " . . . *In cases where*

---

8. See Department of Justice response submitted on behalf of the Panel, page 8.
9. The numerical expression of the range of URFs determined by OEHHA is 1.3×10^{-4} to 2.4×10^{-3} $(\mu g/m^3)^{-1}$. (Department of Justice response for the Panel, Exhibit 4, "Findings of the Scientific Review Panel on 'The Report on Diesel Exhaust' as adopted at the Panel's April, 22, 1998, meeting" ("Findings"), page 5.
10. Health and Safety Code section 39660, subdivision (c).
11. *Id.*

there is no threshold of significant adverse health effects, [OEHHA] shall determine the range of risks to humans resulting from current or anticipated exposure to the substance."[12] (Emphasis added.)

The American Heritage Dictionary (2d college ed. 1982), on page 134, defines "assess" as ". . . [t]o evaluate . . ." and an "assessment" as "[t]he act of assessing." This dictionary, on page 466, also defines "estimate" as "[a] tentative evaluation or rough calculation . . . [a] preliminary calculation . . . [a] judgment based upon one's impressions; opinion." Therefore, an assessment or estimate is not by definition a rule or standard of general application.

The statutory terms "assess" and "estimate" verify that OEHHA's range of URFs is not a rule or standard of general application, but instead is OEHHA's scientific opinion that provides ARB with the necessary background scientific data for ARB to begin to address the issue of whether or not a substance is a TAC. The legislative scheme prohibits ARB from beginning a rulemaking without preliminary research being done by both its staff and OEHHA and having the resultant report validated by the Panel. We also note that it is common practice for state agencies to have staff prepare reports or conduct pre-APA workshops, or both, in order to gather and evaluate information prior to the beginning of a rulemaking. These preliminary activities are not incompatible with the APA.[13]

Health and Safety Code section 39661, subdivision (a)(1), provides that once OEHHA has submitted its evaluation and recommendations to the ARB, ARB "in consultation with, and with the participation of, [OEHHA], shall prepare a report in a form which *may serve as the basis* for regulatory action regarding a particular substance pursuant to subdivisions (b) and (c) of Section 39662." (Emphasis added.)

The phrase "which may serve as the basis for regulatory action" is critical. ARB is not required to take the report (i.e., range of URFs) and duplicate it in regulation. There is no mandate that the substance at issue must be listed. ARB has full regulatory authority to use its discretion in deciding whether or not to list a substance as a TAC. The range of URFs is scientific background data, the functional equivalent of a pre-APA workshop or an agency staff report. The range of URFs, just like any other data or document relied upon, is subject to public review and comment during ARB's rulemaking.

---

12. *Id*.
13. See Government Code sections 11346, subdivision (b), and 11346.45.

As part of the TAC identification process, OEHHA and ARB jointly issued three draft reports. The Executive Summary of the third and final report explains the TAC identification process, gives the dates of all three draft reports and workshops, defines "diesel fuel," identifies three source categories (mobile, stationary area, and stationary point), discusses reductions in pollutant emissions as a result of emission standards and fuel regulations, identifies research studies, describes how exposure to diesel exhaust is difficult to precisely quantify, estimates various outdoor and indoor concentrations of diesel exhaust in California, summarizes health effects based on over 30 epidemiological studies on humans and also animal studies, and summarizes findings by other governmental agencies and scientific bodies. In addition to epidemiological review, a meta-analysis was conducted that " . . . provides strong support for the *hypothesis* that occupational exposure to diesel exhaust is associated with an increased *risk* of lung cancer . . . ."[14] (Emphasis added.)

According to the Executive Summary, both animal and human studies were reviewed, but " . . . OEHHA preferred to *derive* the human risk *estimates* based only upon the epidemiological findings and not the rat data . . ." because ". . . the human data lend[s] more confidence in the *prediction* of human risks than the data from the rat studies because of the uncertainties of extrapolating from rats to humans . . . ."[15] (Emphasis added.) The words "derive," "estimates," and "prediction" underscore that the range of URFs is not a rule or standard of general application. The Executive Summary also explained that two studies, the Garshick et al. (1987a) case-control study and the Garshick et al. (1988) cohort study of U.S. railroad workers, were selected for quantitative risk assessment for the following reasons:

> "[These studies] were selected for quantitative risk assessment because of their quality, their apparent finding of a relationship of cancer rate to duration of exposure and because of the availability of measurements of diesel exhaust among similar railroad workers from the early 1980's in other studies. The case-control study (1987) has an advantage in providing direct information on smoking rates, while the cohort study (1988) has an advantage of smaller confidence intervals in the risk estimates."[16]

Calculations using the two studies " . . . and the *reanalyses of the individual data*

---

14. Department of Justice response for the Panel, Exhibit 6, page ES-22 of the "Executive Summary."
15. *Id*., at page ES-23.
16. *Id*.

of the Garshick *et al.* (1988) cohort study . . . provide *a number of estimates* of unit risk. . . . Because of uncertainties in the actual workplace exposures, OEHHA *developed a variety of exposure scenarios to bracket the possible exposures of interest*. . . ."[17] (Emphasis added.) A table was prepared to present the range of resulting estimates of cancer risk. The Executive Summary of the final report contains "estimates" with qualifiers to clarify "uncertainties" in the relevant science, and is further evidence that OEHHA did not stray from its statutory fact-gathering and analysis duties into establishing a rule or standard of general application.

We conclude that the range of URFs determined by OEHHA is not a standard or rule of general application, does not constitute a "regulation" pursuant to Government Code section 11342.600, and therefore, is not subject to the APA.

Scientific Review Panel

The Association's request also challenges the Panel's determination of a specific URF. Our initial inquiry is whether the Panel is a state agency subject to the APA. The Legislature created a "highly qualified" nine-member Panel in order to ". . . advise [ARB] . . . in their evaluation of the health effects toxicity of substances . . ." and specified the qualifications for the Panel members.[18] Health and Safety Code section 39670, subdivisions (d) and (e), provide that the Panel may ". . . utilize special consultants or establish ad hoc committees, which may include other scientists, to assist it in performing its function . . . ." The members of the Panel are paid by the state on a per diem basis for attending Panel and ARB meetings and other specified expenses. Our independent research did not reveal any evidence that the Panel is not a state agency or is exempt from the APA. The Attorney General's response on behalf of the Panel did not raise these issues. The court in *Poschman v. Dumke* (1973) 31 Cal.App.3d 932, 942, 107 Cal.Rptr. 596, 603, held that an agency created by the Legislature is subject to and must comply with the APA. Therefore, we think that for purposes of this determination, the Panel is a state agency subject to the APA.

The legislative findings and declarations for the Tanner Act contained in Health and Safety Code section 39650 include the following:

> "(d) That the identification and regulation of toxic air contaminants should utilize the best available scientific evidence gathered from the public, private industry, the scientific community, and federal, state, and local agencies, and

17. *Id*., at page ES-24.
18. Health and Safety Code section 39670.

that the *scientific research on which decisions related to health effects are based should be reviewed by a scientific review panel and members of the public*. [Emphasis added.] "

Health and Safety Code section 39661, subdivision (a), requires ARB and OEHHA to submit its report to the Panel for review. Section 39661, subdivisions (b) and (c), provide as follows:

"(b) The [ARB and OEHHA] report, together with the scientific data on which the report is based, shall, with the exception of trade secrets, be made available to the public and *shall be formally reviewed* by the scientific review panel . . . . The panel shall review the scientific procedures and methods used to support the data, the data itself, and the conclusions and assessments on which the report is based. Any person may submit any information for consideration by the panel . . . which may, at its discretion, receive oral testimony. The *panel shall submit its written findings to [ARB]* within 45 days after receiving the report. The panel may, however, petition [ARB] for an extension of the deadline, which may not exceed 15 working days.

(c) If the scientific review panel determines that the health effects report is not based upon sound scientific knowledge, methods, or practices, the report shall be returned to [ARB], and [ARB], in consultation with, and with the participation of, [OEHHA], shall prepare revisions to the report which shall be resubmitted, within 30 days following receipt of the panel's determination, to the scientific review panel which shall review the report in conformance with subdivision (b) prior to a formal proposal by [ARB] pursuant to Section 39662. [Emphasis added.]"

Within 10 working days of receipt of the Panel's findings, ARB must begin the APA rulemaking process by preparing a hearing notice and a proposed regulation for purposes of determining if the substance is a TAC. (Health & Saf. Code, § 39662.) Therefore, the Panel's review and approval must occur before ARB can begin a TAC identification process rulemaking.

In this matter, the Panel submitted 23 Findings to ARB along with a transmittal letter, dated May 27, 1998, that stated "The data, developed and reviewed by OEHHA and ARB, in the scientific risk assessment on exposure to diesel exhaust (Part A) and its health effects (Part B), are extensive and scientifically sound."[19]

19. Department of Justice response for the Panel, Exhibit 4, page 1 of the May 27, 1998, transmittal letter from the Panel.

Even though 23 Findings, adopted by the Panel on April 22, 1998, were submitted to ARB, the Association challenges only Finding 19 which states that:

> "19. There are data from human epidemiological studies of occupationally exposed populations which are useful for quantitative risk assessment. The estimated range of lung cancer risk (upper 95% confidence interval) based on human epidemiological data is 1.3×10^{-4} to 2.4×10^{-3} $(\mu g/m^3)^{-1}$ (Table 2). After considering the results of the meta-analysis of human studies, as well as the detailed analysis of railroad workers, *the [Panel] concludes that* 3×10^{-4} $(mg/m^3)^{-1}$ *is a reasonable estimate of unit risk* expressed in terms of diesel particulate. Thus this unit risk value was derived from two separate approaches which yield similar results. A comparison of estimates of risk can be found in Table 3. [Emphasis added.]"

The characterization of 3×10^{-4} $(\mu g/m^3)^{-1}$ as a "reasonable estimate of unit risk" is a scientific expert opinion. Following the 23 Findings, the Panel concludes "For these reasons, we agree with the science presented in Part A by ARB and Part B by OEHHA in the report on diesel exhaust and the ARB staff recommendation to its Board that diesel exhaust be listed by the ARB as a Toxic Air Contaminant."[20]

There is nothing in Finding 19 that is a rule or standard of general application. It is a scientific expert opinion that is part of the scientific review which triggers a rulemaking by ARB, but it does not mandate the outcome of that rulemaking.

After receiving the Panel's findings, ARB began the rulemaking process by submitting its "Notice of Proposed Action" ("Notice") to OAL on June 2, 1998, which was published in the California Regulatory Notice Register on June 12, 1998. The Notice stated in relevant part " . . . *staff* is *proposing* that the ARB amend section 93000 of Title 17, California Code of Regulations, by adding diesel exhaust to the list of toxic air contaminants with no identified threshold exposure level below which no significant adverse health effects are anticipated." (Emphasis added.) The Notice identified the OEHHA evaluation of the health effects of diesel exhaust, the ARB report on diesel exhaust which included the OEHHA health effects evaluation, and the Panel's findings. The Notice also described the Staff Report which served as the Initial Statement of Reasons ("ISR"). The Notice identified as "technical support documents" the OEHHA health assessment, the ARB's exposure assessment, the public comment letters, and staff responses to those comments prepared by the ARB and OEHHA staff, the Panel's findings, and the Executive Summary which had been approved by the Panel.

---

20. Department of Justice response for the Panel, Exhibit 4, "Findings," page 5.

Government Code section 11346.2, subdivision (b)(2), requires that the ISR identify ". . . each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies in proposing the adoption, amendment, or repeal of a regulation." The documents relied upon and the Staff Report/ISR are subject to public review and comment during the rulemaking process. On July 21, 1999, OAL approved ARB's addition of particulate emissions from diesel-fueled engines to the list of substances identified as TACs in section 93000 of title 17 of the California Code of Regulations. (OAL file no. 99-0610-03S.) This amendment became operative on August 20, 1999.

The URFs were determined by OEHHA and the Panel in the course of compliance with the Tanner Act's statutory mandate that they provide ARB with scientific data in order for ARB to carry out its statutory mandate to identify TACs. OEHHA's range of URFs and the Panel's specific URF provide the scientific basis for ARB's rulemaking. They are not rules or standards of general application.

The Association asserts that the URFs are ". . . making it increasingly likely that diesel-fueled engines will face severe restrictions throughout the State . . . driving alarmist reporting, media campaigns and orchestrated lobbying efforts regarding the assumed dangers of diesel-fueled engines."[21] The fact that the URFs may affect individual purchasing decisions does not in and of itself render URFs rules or standards of general application subject to the APA.

The following hypothetical may be helpful. If an agency issues a scientific report which concludes that its review of current scientific research shows a certain food product causes a risk of cancer, then that scientific opinion is not a rule or standard of general application. The fact that some members of the general public may stop purchasing that item and companies that produce or market that item may have a loss of revenue does not by itself transform the scientific opinion into a rule or standard of general application. However, if an agency states that, based on its scientific opinion, the item that causes a risk of cancer cannot be sold or purchased in the state, then those prohibitions or limitations would constitute a rule or standard of general application, but the scientific opinion that was the basis for the rule or standard would remain non-regulatory.

The Association also asserts that "no other state agency is empowered to ignore or revise the URFs that OEHHA and the [Panel] have formulated and adopted"[22] and

21. Association's request for determination, page 8.
22. *Id*., page 3.

cites to Executive Order W-137-96 issued by former Governor Wilson.[23] The Association quotes directly from the Executive Order that OEHHA is designated "the principal State agency for the coordination of procedures, forms and deadlines related to human health risk assessment from chemicals in the environment" and that "all other state agencies shall defer to [OEHHA] in the performance of their duties in this area."

Deference is not the same as mandating agencies to accept something without any discretion. We note that the Executive Order also states that OEHHA's designation was authorized by Government Code section 11019.6, subdivision (a), which requires other state agencies to defer to the principal state agency identified by the Governor ". . . with respect to procedures, forms, and deadlines, *but not with respect to any other area of authority.*" (Emphasis added.) The range of URFs do not appear on the surface to come within "procedures, forms, and deadlines." Government Code section 11019.6, subdivision (d), cautions that "No part of this section shall be construed to authorize any state agency to adopt or implement procedures, forms, or deadlines in conflict with . . . the Administrative Procedure Act. . . ." Most importantly, it is only the range of URFs determined by OEHHA and the specific URF determined by the Panel that are at issue in this OAL determination,[24] not how other agencies have utilized the URFs[25] or "deferred" to

---

23. *Id*., page 3, footnote 3.

24. The Association raised the following issues that are beyond the scope of our authority in issuing a determination: whether the Panel meeting was "procedurally-abusive," did OEHHA and the Panel exceed their authority by establishing URFs, and are OEHHA's and the Panel's URFs "overstated"? (Association's request for determination, pages 3-8.) OAL does not review alleged underground regulations for compliance with the APA's procedural requirements and with the APA's six substantive standards of Necessity, Authority, Clarity, Consistency, Reference, and Nonduplication. When proposed regulations are submitted to OAL, we review the proposed regulations for compliance with all APA requirements.

25. The Association's request for determination asserts that other governmental entities are utilizing the URFs. The URFs are scientific opinions that are a statutory prerequisite to ARB's statutory TAC identification process. This mandate does not preclude other governmental entities from using those same URFs in similar or other contexts. The governmental entities that the Association asserts are utilizing the challenged URFs are as follows: ARB's amendment of LEV II standards; the South Coast Air Quality Management District's incorporation of the OEHHA/Panel URFs into their multiple air toxics exposure study ("MATES II Report") and the statement that this lays the groundwork for proposed fleetrule regulations that ". . . would force fleets of vehicles, especially trucks to use alternative fuels rather than diesel"; the Attorney General's use of URFs to compel the elimination of diesel-fueled engines and vehicles and also in Proposition 65 cases against grocery store distribution centers in California that would ". . . compel those operators to convert their trucking fleets to alternative fuels . . . ."

    The Association's first supplement dated August 16, 2000, identified the following governmental

OEHHA as the designated principal state agency.

Therefore, the specific unit risk factor determined by the Scientific Review Panel on Toxic Air Contaminants for particulate emissions from diesel-fueled engines does not constitute a "regulation" as defined in Government Code section 11342.600, and therefore, is not subject to the APA.

1999 OAL Determination No. 17

The Association's request relies heavily on 1999 OAL Determination No. 17 ("1999 determination"),[26] which concluded that two parts of the challenged Public Health Goal were subject to the APA: (1) OEHHA's identification of an industrial chemical Di(2-ethylhexl) phthalate ("DEHP") as a teratogen and a reproductive toxicant, and (2) OEHHA's determination that a maximum of 12 parts per billion of DEHP can safely be allowed in drinking water. The 1999 determination also concluded that one part of this Public Health Goal, OEHHA's determination that DEHP is a carcinogen, is a "regulation" within the meaning of the APA, but is not subject to the APA because it is included in the official Proposition 65 list of

---

entities: the ARB's utilization of URFs in a draft report "Proposed Risk Reduction Plan for Diesel-Fueled Engines and Vehicles" ("Risk Reduction Plan") and 13 recommended airborne toxic control measures; the ARB's draft "Risk Management Guidance for the Permitting of New Stationary Diesel-Fueled Engines" ("Permitting Guidance"); South Coast Air Quality Management District ("SCAQMD") fleet rules that ". . . preclude the purchase of diesel-fueled engines by public fleet operators that utilize light and medium duty vehicles, . . .on-road transit buses . . . and on-road refuse collection vehicles . . ." which had as "[t]he purported bases" the Mates II Report which expressly relied on OEHHA and the Panel's URFs; the Butte County Air Quality Management District's denial of a permit "prepared in reliance on the [Panel's] point estimate of risk," i.e., the Panel's specific URF.

The Association's second supplement dated August 18, 2000, identified the Bay Area Air Quality Management District's decision denying operating permits for three new diesel-fueled engines ranging from 54 hp to 17 hp based on the URFs.

The Association's third supplement dated December 8, 2000, identified the following: SCAQMD's additional fleet rules precluding the purchase of diesel-fueled street sweepers and airport ground access vehicles such as vans, shuttles and buses, and heavy- duty trucks based on the Mates II Report; the San Joaquin Valley Air Pollution Control District's proposal to adopt "best available control technology" ("BACT") emission standards for diesel-fueled engines including those used less than 1000 hours per year and mandating the "installation of inordinately expensive particulate matter filter systems on all such 'limited use' engines." The BACT rules are based on OEHHA's range of URFs and the Panel's specific URF.

26. 1999 OAL Determination No. 17 (California Regulatory Notice Register 99, No. 33-Z, August 13, 1999, p. 1575).

chemicals known to the State of California to cause cancer, a list expressly exempted by statute from the requirements of the APA.

The Association refers to this 1999 determination as being ". . . a case on all fours with this one . . . ."[27] The Association asserts that "[t]he rationale [of this 1999 determination] . . . is equally applicable to OEHHA's and the [Panel's] development and adoption of URFs for diesel exhaust."[28] We disagree. Both the statutory framework and rationale in the 1999 determination are distinguishable from the request now being decided.

Health and Safety Code section 116275 et seq. is the California Safe Drinking Water Act. The Health and Safety Code sections quoted below are the versions that were in existence at the time that the 1999 determination was issued on August 6, 1999. Section 116365, subdivision (c), required OEHHA to adopt public health goals ". . . for each drinking water contaminant regulated, or proposed to be regulated, by the [Department of Health Services ("DHS")] pursuant to a primary drinking water standard . . . ." Section 116365, subdivision (a), required the following:

> " . . . [DHS] shall adopt primary drinking water standards for contaminants in drinking water . . . . Each primary drinking water standard adopted by the department shall be set at a level that is as close as feasible to the corresponding public health goal placing primary emphasis on the protection of public health, and that, to the extent technologically and economically feasible meets [specified criteria] . . . ."

In contrast, under the Tanner Act, ARB must begin the TAC risk assessment process by requesting OEHHA to evaluate health effects of a substance.[29] OEHHA does not begin the scientific review of its own volition, but serves rather as a consultant or in an advisory capacity.

Health and Safety Code section 116365, subdivision (a), mandates that DHS set primary drinking water standards for contaminants in drinking water that are adopted by OEHHA " . . . as close as feasible to the corresponding public health goal . . . ." This was characterized in the 1999 determination as the creation of "a strong presumption" that impacts the public's right to meaningful participation in DHS's rulemaking thereby limiting the discretion of DHS and circumscribing the

---

27. Association's request for determination, page 14.
28. *Id.*, page 16.
29. Health and Safety Code section 39660.

scope of influence of public comments.[30]

In contrast, the Tanner Act creates no such presumptions and contains no such limit on ARB's discretion in deciding whether or not to list a substance as a TAC. Once ARB receives OEHHA's evaluations, OEHHA and ARB jointly prepare a report ". . . which *may* serve as the basis for regulatory action."[31] (Emphasis added.) This report ". . . shall . . . be made available to the public . . . . Any person may submit any information for consideration by the panel . . . which may, at its discretion, receive oral testimony."[32] The Tanner Act also requires the ARB to begin a rulemaking within 10 working days of receipt of the Panel's findings, but there is no statutory limit on ARB's discretion. If a substance is identified by ARB as a TAC and adopted as a regulation, then that regulation must also, if possible, establish a threshold exposure level.[33] (Health & Saf. Code, § 39662.)

After the draft reports were published, public workshops were held in September 1994, January 1996, and July 1997. The Panel then held a public meeting in March 1998 to hear from invited scientists with expertise in diesel exhaust.[34] All of this was prior to ARB's rulemaking which included OEHHA and the Panel's findings regarding URFs as part of the Staff Report/ISR which was subject to APA public review and comment.

For the above stated reasons, we find that the 1999 determination is not dispositive because it is distinguishable from this request for determination.[35]

---

30. 1999 OAL Determination No. 17 (California Regulatory Notice Register 99, No. 33-Z, August 13, 1999, p. 1575).
31. Health and Safety Code section 39661, subdivision (a).
32. Health and Safety Code section 39661, subdivision (b).
33. ARB did list particulate emissions from diesel-fueled engines as a TAC in a duly adopted regulation (Cal. Code Regs., tit. 17, § 93000), but did not include a threshold exposure level because the ARB found there was not sufficient available scientific evidence to support an identification of a threshold level.
34. Department of Justice response for the Panel, Exhibit 6, pages ES 4 and 5 of the "Executive Summary."
35. We note that Health and Safety Code section 116365, upon which the 1999 determination is based, was amended effective January 1, 2000 (Stats. 1999, ch. 777, § 1), and that the 1999 determination must now be read in conjunction with this recent amendment. Section 116365, subdivision (c)(2), currently declares as follows:

> "The determination of the toxicological end points of a contaminant and the publication of its *public health goal* in a risk assessment *prepared by the Office of Environmental Health Hazard Assessment are not subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code [the APA.]* The Office of Environmental Health Hazard

Therefore, we conclude that the range of unit risk factors determined by OEHHA and the specific unit risk factor determined by the Scientific Review Panel on Toxic Air Contaminants for particulate emissions from diesel-fueled engines do not constitute "regulations" as defined in Government Code section 11342.600, and therefore, are not subject to the APA.

DATE: August 7, 2001

DAVID B. JUDSON
Deputy Director and Chief Counsel

DEBRA M. CORNEZ
Senior Staff Counsel
Determinations Program Coordinator

_____
BARBARA ECKARD
Senior Staff Counsel

Regulatory Determinations Program
Office of Administrative Law
555 Capitol Mall, Suite 1290
Sacramento, California 95814
(916) 323-6225, CALNET 8-473-6225

Assessment and the department [DHS] shall not impose any mandate on a public water system that requires the public water system to comply with a public health goal. The Legislature finds and declares that the addition of this paragraph by the act amending this section during the 1999-2000 Regular Session of the Legislature *is declaratory of existing law*. [Emphasis added.] "

Facsimile No. (916) 323-6826
Electronic Mail: staff@oal.ca.gov

i:\2001.6